Genzyme Corp rati n
One Kendall Square
Cambridge, MA 02139

JUL 2 5 2002

K021316

ATTACHMENT 1

510(k) Summary Of Safety and Effectiveness Information Upon Which An Equivalence Determination Could be Made

Trade or Proprietary Name:	Genzyme Ultra N-geneous® HDL Cholesterol Reagent and Calibrator
Common or Usual Name:	Homogeneous assay for high density lipoprotein cholesterol
Classification Name:	High density lipoprotein cholesterol test
Manufacturer:	Genzyme Diagnostics One Kendall Square Cambridge, MA 02139-1562

Contact Person: Robert Yocher Vice President, Regulatory Affairs (617) 374-7275 or Barbara Pizza, Manager Regulatory Associate (617) 252-7953

The use of the new Ultra Genzyme N-geneous® HDL Cholesterol in clinical and physician's office laboratory settings is substantially equivalent to the current Liquid N-geneous® HDL Cholesterol Reagent method (I). The new Ultra N-geneous® HDL Cholesterol Kit is a two-reagent homogeneous method for the direct quantitative determination of high density lipoprotein cholesterol (HDL-C) in human serum and plasma.

The new Ultra N-geneous® HDL Cholesterol assay does not contain polyanion or divalent metal, "precipitation reagent". This new method is based on accelerating the reaction of cholesterol oxidase and dissolving HDL selectively using a specific detergent. The users use the reagent in the same manner as the current Liquid N-geneous® HDL Cholesterol Reagent.

Comparative performance studies were conducted using the Ultra N-geneous® HDL Cholesterol Reagent compared to (1) the reference method: the Center for Disease Control (CDC) designated comparison method (DCM) and (2) the current Liquid N-geneous® HDL Cholesterol Reagent method (I). When samples contained triglyceride levels >400 mg/dL, the HDL reference method (ultracentrifugation, chemical precipitation and Abell-Kendall) was performed.

One-hundred and one serum samples, with HDL values between 33.6 and 133.0 mg/dL, were tested at Genzyme Corporation using the Ultra N-geneous® HDL Reagent on the Hitachi 911 Analyzer, the predicate Liquid N-geneous® HDL Cholesterol Reagent method on the Hitachi 911 analyzer. Fifty-two serum samples with HDL values between 32.0 – 133.0 mg/dL were tested using the Ultra N-

geneous® HDL Reagent on the Hitachi 911 Analyzer and at Pacific BioMetrics (Seattle, WA) using the Designated Comparison Method for samples with triglyceride levels ≤400 mg/dL.

	vs. current Liquid N-geneous® HDL (n = 101)	vs. Designated Comparison Method (n = 52)
Slope	0.98	0.99
Intercept (mg/dL)	3.42	2.81
Correlation Coefficient (r)	0.996	0.996
Mean (mg/dL)	56.4	58.3
Standard Deviation (mg/dL)	13.6	15.5
Mean Difference (mg/dL)	2.3	2.0
Mean Percent Difference	4.5	3.9
Range (m/gdL)	33.6 – 133.0	32.0 – 133.0

Precision studies were conducted using the Ultra N-geneous® HDL Cholesterol Test Kit. Both within-run and between-run studies were performed using frozen serum pools at three target levels of HDL cholesterol as determined by the National Cholesterol Education Program (NCEP): <40 mg/dL (low); 40-59 mg/dL (mid); and ≥60 mg/dL (high).

	Low (<40 mg/dL)	Mid (40-59 mg/dL)	High (≥60 mg/dL)
N	20	20	20
Sample Range (mg/dL)	32.4 – 33.5	50.1 – 50.9	99.4 – 102.4
Mean (mg/dL)	32.9	50.6	101.4
SD (mg/dL)	0.3	0.2	0.7
%CV	0.8	0.5	0.7

	Low (<40 mg/dL)	Mid (40-59 mg/dL)	High (≥60 mg/dL)
n	40	40	40
Sample Range (mg/dL)	31.6 – 33.5	48.4 – 51.1	97.6 – 102.2
Mean (mg/dL)	32.8	50.0	100.1
SD (mg/dL)	0.4	0.7	1.1
%CV	1.3	1.5	1.1

In separate comparative performance studies, three physician office laboratories (POL) analyzed separate sets of 40 serum samples using the lyophilized format of Genzyme's N-geneous™ HDL Cholesterol Reagent Kit. Split samples from the same 40 specimens were also analyzed at Genzyme, which acted as the reference laboratory. The correlation coefficient between the reference testing site and the POL testing sites for this study were:

Parameter	Site #1	Site #2	Site #3
Slope	1.11	1.12	0.93
Intercept (mg/dL)	-1.44	-5.90	1.25
Correlation Coefficient (r)	0.97	0.99	0.99

In the same study, the three POL sites compared their Genzyme N-geneous™ HDL Cholesterol Reagent Kit results to their respective current HDL methods for each of these 40 patient samples. The correlation coefficient for these comparisons were:

Parameter	Site #1	Site #2	Site #3
Slope	0.88	1.05	0.77
Intercept (mg/dL)	2.90	-1.32	11.1
Correlation Coefficient (r)	0.97	0.99	0.98

Precision studies were conducted using the lyophilized N-geneous™ HDL Cholesterol Test Kit. Both within-run and between-run studies were performed using frozen serum pools at three target levels of HDL cholesterol as determined by the National Cholesterol Education Program (NCEP): <40 mg/dL (low); 40-59 mg/dL (mid); and ≥60 mg/dL (high). It was determined that each POL site achieved the NCEP goals of CVs ≤5% at ≥42 mg/dL, and ≤1.7 mg/dL SD at <42 mg/dL, when using the Genzyme N-geneous™ HDL Cholesterol Kit.

These data demonstrate that the performance of the Ultra N-geneous® HDL Cholesterol Reagent in both the clinical and physician office laboratories is substantially equivalent to the performance of the Liquid N-geneous® HDL Cholesterol Reagent and CDC Designated Comparison Methods.

In lieu of a 510(k) statement under 513(i) of the Act, this information is provided as a 510(k) summary for disclosure to any other persons/companies without the specific written authorization from Genzyme Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 2 5 2002

Mr. Robert Yocher
Vice President Regulatory Affairs
Genzyme Corporation
One Kendall Square
Cambridge, MA 02139-1562

Re: k021316
Trade/Device Name: Ultra HDL Cholesterol
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class II
Product Code: LBS; JIS
Dated: July 8, 2002
Received: July 9, 2002

Dear Mr. Yocher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Genzyme Corporation
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Cambridge, MA 02139

CONFIDENTIAL

Ultra N-geneous® HDL Cholesterol
Reference No. K021316
July 8, 2002

510(k) NUMBER (if known): K021316

DEVICE NAME: Ultra HDL Cholesterol

INDICATIONS FOR USE:

Reagent:
For the quantitative determination of high-density cholesterol lipoprotein cholesterol in human serum or plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus, atherosclerosis and various liver and renal diseases).

For In Vitro Diagnostic Use

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021316

Calibrator:
For calibration of the Ultra HDL Cholesterol assay.
For In Vitro Diagnostic Use

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ____
(Optional Format 1-2-96)